Research Proposal Guidelines

Note: Documentation used for IRB approval or other application processes involved with this project may be used for some or all of these research proposal requirements, so long as all items in this guideline are addressed. While organization is flexible, it is easier for the Utah Tracking Program to ensure completeness if the documentation follows these guidelines.

1. **PROJECT PERONNEL AND ADMINISTRATION:** List the name and contact information of the principle investigator, principle collaborators, and all participating personnel. Include a summary of related studies previously conducted by the project personnel. Describe all agencies supporting this project. Synopses or portfolio documents can be used as part of the agency descriptions. Attach Curriculum Vitae (CV) or biographical sketches for the principle investigator, study director, project coordinator/manager, and principle collaborators. Include all participating personnel from any collaborating agencies involved in this study.

2. **EXECUTIVE SUMMARY/ABSTRACT:** Provide a brief (300 words) executive summary of the project. The summary should include a hypothesis statement, data and methods for data connections, analytical methods, anticipated analytical results, and details of any anticipated publications, presentations, or other distributions of the research results and reports.

3. **FUNDING:** Briefly describe how this project is or will be funded.

4. **BACKGROUND:** Briefly describe (500 words) the literature background supporting and guiding this project. Background should describe the population at risk, known and hypothetical exposure pathways, and environmental hazards related to the health outcome to be studied.

5. **OBJECTIVES:** Briefly outline the objectives, problem statement or hypothesis, anticipated outcomes, significance of the results, knowledge gaps this study is intended to fill, and the importance of this study.

6. **STUDY DESIGN, EXPERIMENTAL PLAN AND METHODS:** Describe the study design, experimental plan, and analytical methods to be used to manipulate and link data topics and/or analyze the data for this project in order to achieve the objectives. If appropriate, discuss the environmental hazards, exposure pathway, and health outcomes to be studied in this project. Describe the study population, study area, and study period. Describe selection, inclusion criteria, and exclusion criteria for data records to be used. Describe the criteria for accepting or rejecting the hypothesis. Describe sampling and data connection protocols. Describe anticipated biases or confounding that may impact the study results and how those biases and confounding factors will be accounted for. Describe the statistical methods to be used, how those methods will be interpreted, and the appropriateness of those methods to the hypothesis or study problem. Justify modifications to standard methods. Outline anticipated weaknesses, study constraints, and limitations in the chosen study design, experimental plan, and methodology. Describe proposed remedies or alternative approaches for those weaknesses.

7. **DATA MANAGEMENT AND PROTECTION:** Describe the access, use, protection, and final disposition of data used for this project. Describe employee training related to the access, use, protection, and management of data provided to all personnel involved in this project. Describe policies and procedures that are and will be used to assure non-disclosure of the confidential data. Describe policies and procedures that are and will be used to manage security intrusions. Describe

policies for electronic storage of data. Describe policies and procedures for paper copies of data, work products and records. Describe study protocol change management and procedures. Describe the institutional oversight and review process used for this research proposal.

8. **UTAH TRACKING PROGRAM PARTICIPATION:** Describe anticipated roles, responsibilities, activities, or requirements for the Utah Tracking Program and/or the data owners (agencies who provide data to the Utah Tracking Network).

9. **TIMELINE:** Describe the proposed timeline for this project.

10. **PROPOSED PUBLICATION OF RESULTS:** Briefly describe the anticipated means for publishing or reporting the findings from this project. Describe the intended audience(s) of the publication. Describe the anticipated time for publication(s). Public presentations are defined as any published paper, abstract, brief, report, letter, poster, speech, article, or other presentation that discloses the data, information about the data, information about the data owner, or information about the Utah Tracking Network that is made available to the public (including organizational peers) through peer-reviewed or un-reviewed journals, magazines, newsletters, professional or public conferences, public or organizational meetings, or other forums or events to which persons not directly associated to the research project (i.e., any individual who has not submitted a Data-use Agreement Form and received SRB approval) could be in attendance or have access.

11. **HUMAN SUBJECTS:** The Utah Tracking Program does NOT provide identifying information on human subjects. Projects that require case identifying information will need to coordinate directly with the data owner for those data. If the project intends to link Utah Tracking Program data with identifiable case data (regardless of the data topic), briefly describe those linkages and the Human Subjects assurances required for IRB approval. Describe the IRB approval process being pursued or completed. Include the IRB chair contact information.

12. **BIBLIOGRAPHY:** The standard bibliography format standards can be used for this section.